REMARKS

Reconsideration of the present application in light of the above amendments and the following remarks is respectfully requested. Claims 22-24 and 26-32 are pending. Claim 24 has been deleted and claims 22, 28 and 29 have been amended for clarification and solely to expedite prosecution without acquiescing to any rejection. Claims 30-32 have been added. Support for the amendments can be found, for example at line 11, page 6, lines 16-23, page 9 and line 20, page 7 for the chemical analogues. Support for new claims is provided in the existing claim set and at, for example page 6, line 11. No new matter has been added.

Objection re: "Brief Description of the Drawings"

Please amend the specification at page 18, line 13, by replacing the heading "In the Figures:" with the heading "***Brief Description of the Drawings***". The Examiner's objection regarding the drawings section is now believed to be overcome.

Rejection under 35 U.S.C. § 112, Second Paragraph, Claim 22

Claim 22 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. In particular, the Action alleges the phrase "analogous or homologous" would not be understood by one of ordinary skill in the art and as such, renders the claim unclear.

Applicants respectfully traverse this ground for rejection and submit claim 22 has been amended for clarification and, while not acquiescing to this rejection, the phrase "analogous or homologous" has been removed from the claim. Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 112, Second Paragraph, Claims 23-24 and 26-29

Claims 23-24 and 26-29 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. In particular, the Action alleges the phrase "analogous or homologous" in independent claim 22, from which claims 23, 24, and 26-29 depend, is unclear.

Also, the Action alleges claim 29 is unclear since QVAX is a preparation of whole bacterial cells, rather than "antigenic components".

Applicants respectfully traverse this rejection and submit the claims are clearly understood by one of ordinary skill in the art. However, solely to expedite prosecution and without acquiescing to the rejection, claim 22 has been amended to remove the phrase "analogous and homologous." Applicants further submit claim 29 has been amended for clarification to replace "antigenic component" with "*Coxiella burnetii.*" Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 112, First Paragraph, Claims 22-24 and 26-29

Claims 22-24 and 26-29 stand rejected as allegedly not being enabled by the specification as filed. In particular, the Action alleges the phrase "analogous or homologous" is unclear as to the parameters or characteristics of such components.

Applicants respectfully traverse this ground for rejection and submit the claims are fully supported by the specification such that one of ordinary skill in the art would be enabled to practice the claimed invention. Nonetheless, solely to expedite prosecution and without acquiescing to the rejection, independent claim 22 has been amended to remove the phrase "analogous or homologous." Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 102(b), Claims 22, 23 and 26-28

Claims 22, 23 and 26-28 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Zhang *et al.* (Acta Virologica 38: 327-332, 1994) or Gajdosova *et al.* (Acta Virologica 38: 339-344, 1994) or Williams *et al.* (Infect. Immun. 51: 851-858, 1986) as evidenced by Levy *et al.* (Eur. J. Epidemiol. 5: 447-453, 1989) or Roue *et al.* (Lancet 341: 1094-1095, 1993). In particular, the Action states the preamble "for the treatment of an autoimmune disease in a mammal" merely represents an intended use and is not given patentable weight unless Applicants can show a manipulative difference.

Applicants traverse this ground for rejection and submit the claims are not anticipated by the cited references but instead, are novel in light of them. Nonetheless, solely to expedite prosecution and without acquiescing to the rejection, Applicants have amended independent claim 22 to remove the phrase "in the manufacture of a medicament" and as such, the claim recites a method of treatment of an autoimmune disease in a mammal that clearly has a manipulative difference over the cited references.

Applicants maintain none of the cited references anticipate the currently claimed invention. In particular, Zhang *et al.* examine an outer membrane protein isolated from phase I *Coxiella burnetii*, but do not disclose a method for treatment of an autoimmune disease in a mammal. Furthermore, Applicants submit that while Gajdosova *et al.* immunized mice with whole cells and membrane components of *Coxiella burnetii*, they do not disclose the use of Coxiella burnetii as a treatment of an autoimmune disease in a mammal; Williams *et al.* disclose a vaccine for Q fever but do not disclose the use of such vaccine in the treatment of an autoimmune disease in a mammal; Levy *et al.* teach two autoimmune markers in Q fever (smooth muscle antibodies and cold agglutinins), however, they show no correlation between Q-fever and smooth muscle antibodies titers and kinetics. *See* line 8-9, Abstract, Measurements and Main Results. Finally, Roue *et al.* studied a patient afflicted with Q-fever but was <u>not</u> suffering from autoimmune disease as a result. Applicants submit mere speculation of a nexus between autoimmunity and Q-fever does not anticipate the presently claimed invention of the treatment of an autoimmune disease in a mammal using one or more antigenic components of *Coxiella burnetii*.

Applicants further submit the Federal Circuit has held that a claim is anticipated by cited references only if each and every element of the claim is found expressly or inherently in a single reference. *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.*, 814 F.2d 628, 2 U.S.P.Q.2d 1051 (Fed. Cir. 1987). Applicants submit none of the cited references disclose the presently claimed invention. Accordingly, Applicants respectfully request the rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 102(b), Claims 22, 23, 26 and 29

Claims 22, 23, 26 and 29 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Izzo *et al.* (Clin. Exp. Immunol. 85: 98-108, 1991) or Izzo *et al.* (J. Infect. Dis. 157: 781-789, 1988). In particular, the Action alleges both of the cited references teach a method of using Q-VAX in the production of a medicament.

Applicants traverse this ground for rejection and submit neither Izzo *et al.* reference disclose a method of treatment of an autoimmune disease in a mammal, as stated in the claimed invention. Applicants submit both cited references disclose vaccines for Q-fever but neither disclose the treatment of an autoimmune disease in a mammal with a vaccine or any antigenic components of *Coxiella burnetii*. Applicants submit the independent claim 22 has been amended for clarification and solely to expedite prosecution and without acquiescing to the rejection. Applicants thus submit the cited references do not disclose each and every element in the presently claimed invention. Accordingly, Applicants submit the presently claimed invention is not anticipated by the cited references and respectfully request the rejection be withdrawn.

Rejection under 35 U.S.C. 102(b), Claims 22-24, 26-28

Claims 22-24 and 26-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by Qin *et al.* (J. Immunol. 150:2072-2080, 1993) as evidenced by Vodkin *et al.* (J. Bacteriol. 170: 1227-1234, 1988) and Edgington (Biotechnology 13: 1442-1444, 13 Dec. 1995). In particular, the Action states the cited references disclose using antigenic components of *Coxiella burnetii* in the manufacture of a medicament.

Applicants respectfully traverse this rejection and submit none of the cited references anticipate the presently claimed invention. Applicants submit that while Qin *et al.* study the use of Complete Freund's Adjuvant and in particular, the mycobacterial cell wall component of the adjuvant, in the prevention and treatment of diabetes in nonobese diabetic mice, the cited reference does not disclose a method of treatment of an autoimmune disease in a mammal using antigenic components of *Coxiella burnetii*. Furthermore, Applicants submit the use of Complete Freund's Adjuvant did not prevent or reverse autoimmunity as evidenced by

destruction of islet tissue in the diabetic mice. Applicants submit Example 3 of the instant specification describes a successful method of treating autoimmune disease in a mammal using components of *Coxiella burnetii*. Thus, Applicants submit Qin *et al.* do not anticipate the presently claimed invention.

Applicants submit that Vodkin *et al.* disclose polypeptides of Coxiella burnetii that may be used in a vaccine, and Edgington discusses generally the use of heat shock proteins in the pharaceutical industry, but neither reference discloses a method of treatment of an autoimmune disease in a mammal. Applicants submit independent claim 22 has been amended for clarification and solely to expedite prosecution but without acquiescing to the rejection to remove the phrase "in the manufacture of a medicament". Applicants submit the presently claimed invention is not anticipated by any of the cited references and accordingly, respectfully requests the rejection be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 22-24 and 26-28 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Qin *et al.* (J. Immunol. 150:2072-2080, 1993) in view of Vodkin *et al.* (J. Bacteriol. 170: 1227-1234, 1988), Edgington (Biotechnology 13: 1442-1444, 13 Dec. 1995), and Barnes *et al.* (WO 87/06590). In particular, the Action alleges the cited references—taken as a whole—teach a method of manufacture of a medicament.

Applicants respectfully traverse this ground for rejection and submit one of ordinary skill in the art would not consider the presently claimed invention obvious in light of the cited references. Applicants submit independent claim 22 has been amended for clarification and the phrase "manufacture of a medicament" has been removed solely to expedite prosecution but without acquiescing to the rejection.

Applicants submit the Federal Circuit has held a claim is only obvious in light of the art when something provides suggestion or motivation for one of ordinary skill in the art to combine the references in order to arrive at the presently claimed invention. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Applicants submit no such suggestion or

motivation exists in the cited references. Accordingly, Applicants respectfully request the rejection be reconsidered and withdrawn.

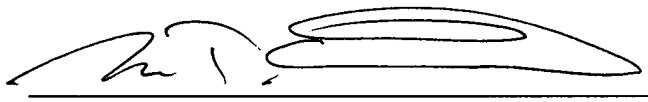
The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

William Butler Cowden et al.

Seed Intellectual Property Law Group PLLC



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